

### **Remarks**

The present response is submitted in reply to the Office action issued on August 3, 2009. Claims 1-8 are pending in this application and each has been rejected by the present Office action. By the present response, claim 1 has been amended, claim 8 has been canceled and claims 10-16 are new. Claim 1 has been amended to more distinctly specify the polymer types that may be used for producing the matrix layer. This amendment is based on former claim 8, now deleted. Polyethylenes, polyurethanes, rubbers and silicone rubbers have been not included in the group defining the matrix polymers.

New claims 10-16 have been added. Claims 10-12 are based on claim 6. New independent claim 13 represents a combination of claim 1 and new claims 10-12. New dependent claim 14 corresponds to former claim 8 (now deleted). New dependent claims 15 and 16 are also based on former claim 8, but refer specifically to natural polymers (claim 15) and synthetic polymers (claim 16). In claim 16, the group of polymers is defined in the same way as in amended claim 1, i.e., excluding polyethylenes, polyurethanes and rubbers, silicone rubbers.

No new matter has been added. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks.

### **Rejection of claim 6 under 35 U.S.C. 112, second paragraph**

Claim 6 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner states that "gel-like" is

ambiguous.

The Applicants respectfully disagree and request reconsideration of this rejection. For example, “gel-like” is supported and clarified by the present specification, such as at paragraph [0039]. Moreover, U.S. Patent No. 5,716,636 (Horstmann, et al.) which is cited by the Examiner in the present Office action, includes the similar term “film-like” (claim 9; column 3, line 47). Additionally, a submission of “gel-like” in the Google® search engine yielded about 20,100,000 hits. Therefore, the term “gel-like” is not ambiguous and would be understood by one skilled in the art. Withdrawal of this rejection is requested.

**Rejection of claims 1-9 under 35 U.S.C. 103(a)**

Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,244,677 (Kreckel, et al.) in view of U.S. Patent Nos. 3,655,918 (Lindquist, et al.) and 5,716,636 (Horstmann, et al.) as evidenced by U.S. Patent No. 4,650,817 (Allen Jr., et al.). According to the Examiner, Kreckel, et al. teach a transdermal drug delivery device (i.e., bandage strips) having a drug formulation that is stored in a punched-out cavity of foam material, such as polyethylene foam layer 18. Additionally, according to the Examiner, the adhesive die-cut article of Kreckel, et al. has an external contour which comprises adhesive layer 19 with an internal cut-out having a contour, wherein the external contour of the adhesive die-cut article has no common point with the contour of the internal cut-out. The Examiner further states that the die-cut article of Kreckel, et al. has a layer of foam having punched out reservoir having an internal cut-out which is congruent with the internal cut-out in the adhesive layer, as well

as a protective film (i.e., covering film) covering the composite of matrix layer, adhesive layer and the internal cut-out.

The Examiner states that Kreckel, et al. fail to teach the foam layer (i.e., matrix layer) being a compacted material and specific pharmaceutical active ingredient.

However, the Examiner refers to Lindquist, et al. for teaching a conformable adhesive sheet that has improved conformability and splitting resistance and can be used as surgical drape or as a bandage, and that the surgical tape of Lindquist, et al. comprises compressed foam web which the Examiner interprets to meet the present claim requirement of “matrix layer being a compacted material.”

Allen Jr., et al. is referenced to show that in adhesive bandage dressing art, polyethylene foam and polyurethane foams are functionally equivalent in the formation of backing.

The Examiner thus concludes that it would have been obvious to provide the matrix layer of Kreckel, et al. as being a compacted material, motivated by the desire to provide sufficient tensile strength and to provide enhanced peel and splitting resistance.

The Examiner also states that Kreckel, et al. as modified by Lindquist, et al. is silent as to teaching the specific pharmaceutical active ingredient. However, the Examiner refers to Horstmann, et al. for teaching a transdermal therapeutic system comprising active substance acetylsalicylic acid. In this regard, the Examiner concludes that it would have been obvious to select the pharmaceutical active ingredient such as acetylsalicylic acid as taught by Horstmann, et al. and used in the invention of Kreckel, et al. because selection of a known material based on its suitability for its intended use

establishes *prima facie* obviousness.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kreckel, et al. in view of Lindquist, et al. and Horstmann, et al. as evidenced by Allen Jr., et al. and further in view of U.S. Patent No. 5,232,702 (Pfister, et al.). According to the Examiner, Kreckel, et al. in view of Lindquist, et al. and Horstmann, et al. fail to teach the specific adhesive as recited in present claim 7. However, the Examiner refers to Pfister, et al. for teaching a silicone pressure sensitive adhesive (PSA) that is compatible with drugs, excipients, co-solvents and skin penetration enhancers. Additionally, the Examiner notes that the PSA of Pfister, et al. includes cohesive strengthening agent which helps to maintain the adhesive on the substrate, while reducing cold flow. The Examiner thus concludes that it would have been obvious to select the silicone PSA of Pfister, et al. for use in the invention of Kreckel, et al., motivated by the desire to provide the adhesive that has improved cohesive strength and stability.

The applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The Applicants submit that each and every feature recited in the present claims, as amended herein, are not set forth in Kreckel, et al. alone or in combination with the other cited prior art. Moreover, the Applicants do not believe one skilled in the art would have had any motivation to amend or modify the invention of Kreckel, et al. to arrive at the presently

claimed invention.

As noted above, the Examiner states that Lindquist, et al. provide motivation to use compressed foam in the device of Kreckel, et al. and that Allen Jr., et al. further teach polyethylene foam and polyurethane foam as being functionally equivalent. As explained above, polyethylene and polyurethane are no longer recited in claim 1. Moreover, no such functional equivalence has been demonstrated for the polymers currently recited in claim 1, as amended herewith. It is noted that “rubbers, silicone rubbers” have also been excluded from claim 1.

Regarding new dependent claims 10-13, it is noted that Kreckel, et al. only teach filling materials that are either low-viscous solutions (col. 2, line 63), microemulsions (col. 3, lines 22-23), ointments or pastes (col. 4, lines 35-36), but not gels, powdery preparations or fusible materials as presently claimed.

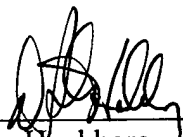
Clearly, each and every feature of the present invention as recited in claims 1-7 and 10-16 (as amended herein) is not set forth in the prior art references. Moreover, the Applicants believe that Kreckel, et al. do not provide any suggestion or motivation to modify the device set forth therein to make up for the aforementioned deficiencies and to subsequently arrive at the presently claimed invention. Therefore, withdrawal of this rejection is strongly requested.

### **Conclusion**

In light of the foregoing claims and arguments, it is believed that the present application is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: November 2, 2009

By:   
D. Peter Hochberg  
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.  
1940 E. 6<sup>th</sup> St. - 6<sup>th</sup> Floor  
Cleveland, OH 44114-2294  
(216) 771-3800  
DPH/SM